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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,504	07/31/2001	R. Martin Emanuele	19720-0625 (42896-261843)	3166

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Jeffery B. Arnold
KILPATRICK STOCKTON LLP
SUITE 2800
1100 Peachtree Street
Atlanta, GA 30309-4530

EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,504

Applicant(s)

EMANUELE ET AL.

Examiner

Richard Schnizer

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims ~~1-18, 20-22, 28-30, and 34-36~~, drawn to therapeutic compositions

1-4, 6, 7, 9-12,
14, 15, 17, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 31, 32, 33, 35, 36, 37, 38

comprising a non-nucleic acid compound capable of altering nucleic acid function
admixed with a block copolymer, classified in class 514, subclass 1.

- II. Claims 1-18, ~~20-22, 28-30, and 34-36~~, drawn to therapeutic compositions

1-18

comprising a gene capable of altering nucleic acid function admixed with a block
copolymer, classified for example in class 536, subclass 23.5.

- III. Claims 1-18, ~~20-22, 28-30, and 34-36~~, drawn to therapeutic compositions

1-18

comprising an oligonucleotide, triplex DNA compound, or ribozyme capable of
altering nucleic acid function admixed with a block copolymer, classified for
example in class 536, subclass 24.31.

- IV. Claims 19, ~~23-27, 31-33, 37, and 38~~, drawn to methods for delivering to an animal

19-22, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38

a non-nucleic acid compound capable of altering nucleic acid function admixed
with a block copolymer, classified in class 514, subclass 1.

- V. Claims 19, ~~23-27, 31-33, 37, and 38~~, drawn to methods for delivering to an animal

19-38

a gene compound capable of altering nucleic acid function admixed with a block
copolymer, classified in class 514, subclass 44.

Rejection

Rejection
v. d. v. i.

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- VI. Claims 19, ~~23-27, 31-33, 37,~~ and 38, drawn to methods for delivering to an animal an oligonucleotide, triplex DNA compound, or ribozyme capable of altering nucleic acid function admixed with a block copolymer, classified in class 514, subclass 44. 1a-38

Claims 1-18, 20-22, 28-30, and 34-36 are generic to a plurality of patentably distinct inventions set forth as groups I-III. Claims 19, 23-27, 31-33, 37, and 38 are generic to a plurality of patentably distinct inventions set forth as groups IV-VI. Claims in the elected group will be examined only to the extent that they are defined by that group.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are related to inventions IV, V, and VI, respectively, as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case The compositions of groups I-III could be used for delivery to cells in vitro, rather than to an animal..

The inventions have been restricted on the basis of the compound admixed with the block copolymer. These compounds include any compound capable of altering nucleic acid function. For the purpose of restriction this genus has been divided into three groups: non-nucleic acid compounds, genes, and a group consisting of oligonucleotides, ribozymes, and triple helix forming nucleic acids. Non-nucleic acid compounds are distinct from genes, oligonucleotides,

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ribozymes, and triple helix compounds because they must by definition have a different structure, and therefore a different mode of action. Similarly, genes are distinct from oligonucleotides, ribozymes, and triple helix compounds because they have a different mode of action. Genes encode and express gene products which can alter the function of other genes, whereas oligonucleotides, ribozymes, and triple helix compounds encode no expressible product and must affect gene expression through a materially different process by physical interaction with some portion of the gene expression apparatus. In contrast, gene function-altering genes can only exert their influence through the activity of a gene product. For these reasons these nucleic acid function altering compounds are distinct from each other, as are the methods requiring their use.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 103-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is usually in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.



JAMES KETTER
PRIMARY EXAMINER